

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P04-74	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/010566	International filing date (day/month/year) 16.07.2004	Priority date (day/month/year) 17.07.2003
International Patent Classification (IPC) or national classification and IPC A61L17/00, A61B17/04, 17/08		
Applicant GUNZE LIMITED		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table><tr><td><input checked="" type="checkbox"/></td><td>Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/></td><td>Box No. II</td><td>Priority</td></tr><tr><td><input type="checkbox"/></td><td>Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/></td><td>Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VIII</td><td>Certain observations on the international application</td></tr></table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report																								
Name and mailing address of the IPEA/JP	Authorized officer																								
Facsimile No.	Telephone No.																								

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
 - ☐ international search (Rule 12.3 and 23.1(b))
 - ☐ publication of the international application (Rule 12.4)
 - ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☒ the international application as originally filed/furnished
 - ☐ the description:
 - pages _____ as originally filed/furnished
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____
 - ☐ the claims:
 - nos. _____ as originally filed/furnished
 - nos.* _____ as amended (together with any statement) under Article 19
 - nos.* _____ received by this Authority on _____
 - nos.* _____ received by this Authority on _____
 - ☐ the drawings:
 - sheets _____ as originally filed/furnished
 - sheets* _____ received by this Authority on _____
 - sheets* _____ received by this Authority on _____
 - ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages _____
 - ☐ the claims, nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages _____
 - ☐ the claims, nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>1-11</u>	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	<u>1-11</u>	NO
Industrial applicability (IA)	Claims	<u>1-11</u>	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
1. JP 8-47526 A			
2. JP 8-33641 A			
3. Tatsuo Adachi (editor), "Sen'i kougaku. II. Henso", Jikkyou Shuppan, 1973, pp. 38 and 39			
4. JP 2001-70433 A			
5. JP 9-308635 A			
Claims 1-5, 10 and 11 (documents 1 and 3)			
<p>Document 1 discloses a method such as temporary stitching and then removing the stitches as a method for joining a sheet-like body constituting suture prosthetic material (paragraphs 14, 15, 23 and 24). Since thread looping stitching (single loop stitch) is a common and widely known method for temporary stitching, as disclosed in document 3, a person skilled in the art could easily conceive of using thread looping stitching, which is a typical method for temporary stitching, for joining a sheet-like body constituting suture prosthetic material in document 1. In addition, the fact that withdrawal is easier if thread looping stitching is adopted instead of the running stitch specifically described in document 1 is obvious from the looping structure, so that the effect of this feature cannot be said to be surprising.</p>			

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Moreover, having a handle portion on the sheet part to be removed outside the body during surgery so as to facilitate removal is merely an option available to a person skilled in the art.

Claim 6 (documents 1-4)

Looping the ends of the thread joining a sheet-like body constituting suture prosthetic material is already practiced in the field of suture prosthetic material, as disclosed in documents 2 and 4.

Claims 7-9 (claims 1, 3 and 5)

Document 5 discloses securing the ends of the thread joining a suture prosthetic material such that they do not come loose (paragraph 9), and the method for preventing fraying of the ends of the connecting threads can be suitably decided by a person skilled in the art.

Claims 1, 2, 5, 6, 10 and 11 (documents 2 and 3)

Document 2 discloses making a sheet-like body constituting a suture prosthetic material by using temporary stitching, and then removing the stitches after surgery (paragraphs 7 and 19). Since additionally thread looping stitching (single loop stitch) is common and widely known as a method for temporary stitching as disclosed in document 3, a person skilled in the art could easily conceive of using thread looping stitching for joining a sheet-like body constituting suture prosthetic material in document 2. Fitting a handle component to the sheet part to be removed outside the body during surgery so as to facilitate removal is also merely an option available to a person skilled in the

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art.

Claims 3 and 4 (documents 1-3)

Document 1 discloses a sheet-like body constituting a suture prosthetic material having a structure in which a sheet formed from biodegradable and absorbable material is united with an stretchable knitted fabric.

Claims 7-9 (documents 2, 3 and 5)

Document 5 discloses securing the ends of the thread joining a suture prosthetic material such that they do not come loose (paragraph 9), and the method for preventing fraying can be suitably decided by a person skilled in the art.